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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/037,254

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Jeffrey H. Burbank

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PATENT DEPARTMENT  
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EXAMINER

ASTORINO, MICHAEL C

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/037,254

Applicant(s)

BURBANK ET AL.

Examiner

Michael C. Astorino

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3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 and 9-48 is/are pending in the application.
- 4a) Of the above claim(s) 7-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 04 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Examiner acknowledges the election of Invention I, claims 1-6 and 9-48.

#### ***Specification***

The disclosure is objected to because of the following informalities: page 9, line 12 “5. blood oxygen, which” is not a completed sentence.

Appropriate correction is required.

The attempt to incorporate subject matter into this application by reference to “Method and Apparatus for Leak detection in a Fluid line,” on page 23, lines 21-22, is ineffective because the reference document is not clearly identified as required by 37 CFR 1.57(b)(2)). The applicant should include the Patent Application number and if appropriate the US Patent number.

The incorporation by reference will not be effective until correction is made to comply with 37 CFR 1.57(b), (c), or (d). If the incorporated material is relied upon to meet any outstanding objection, rejection, or other requirement imposed by the Office, the correction must be made within any time period set by the Office for responding to the objection, rejection, or other requirement for the incorporation to be effective. Compliance will not be held in abeyance with respect to responding to the objection, rejection, or other requirement for the incorporation to be effective. In no case may the correction be made later than the close of prosecution as defined in 37 CFR 1.114(b), or abandonment of the application, whichever occurs earlier.

Any correction inserting material by amendment that was previously incorporated by reference must be accompanied by a statement that the material being inserted is the material incorporated by reference and the amendment contains no new matter. 37 CFR 1.57(f).

### ***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: **40, 45, 50, and 55 (in figure 1A); 320 and 355 (in figure 1B); 145 (in figure 1C); 515 (in figure 9)**. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1-6 and 9-48 are rejected under 35 U.S.C. 102(e) as being anticipated by**

**O'Mahony et al. US Patent Number 6,585,675 B1.**

In regards to claim 1, O'Mahony et al. teaches *"1. A method of detecting a loss of integrity in a blood circuit supplying blood to a patient, comprising the steps of: detecting a leak in at least two independent ways to generate at least two leak detection signals; deriving at least one composite signal responsive to said two leak detection signals; generating an alarm signal responsively to said at least one composite signal."* See column 15, lines 55-65 and column 20, lines 16-27; see below)

The above logic function is a reliable detection of a withdrawal line disconnection, while avoiding false alarms due to blood pressure measurements with blood pressure cuffs. For example, a false alarm could be generated when blood pressure cuffs are pressurized which causes an increased venous pressure and in turn lower withdrawal pressure. **The lower withdrawal pressure caused by a blood pressure cuff might be interpreted by the controller as a disconnection resulting in false alarms except for the logic requirement of air being detected.**

The monitoring CPU 714 provides a safety check that independently monitors each of the critical signals, including signals indicative of blood leaks, pressures in blood circuit, weight of filtrate bag, motor currents, air in blood line detector and motor speed/position. The monitoring CPU has stored in its memory safety and alarm levels for various operating conditions of the ultrafiltrate system. By comparing these allowable preset levels to the real-time

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operating signals, the monitoring CPU can determine whether a safety alarm should be issued, and has the ability to independently stop both motors and reset the motor controller and controller CPU if necessary.

2. A method as in claim 1, wherein said step of deriving includes calculating a probability of a leak responsively to said at least two detection signals. (When the alarm is triggered the probability of a leak is derived to be unacceptable)

3. A method as in claim 1, wherein said step of deriving includes combining said at least two leak detection signals such that a sensitivity of detection of a leak is enhanced. (See column 15, lines 55-65, wherein blood pressure and air in blood line is combined to determine if an alarm is false).

4. A method as in claim 3, wherein said step of calculating includes applying said leak detection signals to a network classifier. (The use of a alarm or false alarm as disclosed by the cited reference is indicative of a network classifier)

5. A method as in claim 1, wherein said step of deriving includes applying a respective weight to said at least two leak detection signals and adding them. (Inherent via disclosure in column 15, lines 55-65, wherein blood pressure and air in blood line is combined to determine if an alarm is false).

6. A method as in claim 1, wherein said step of detecting includes sensing a presence of fluid outside said blood circuit and detecting a presence of air inside said blood circuit. (Inherent via

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disclosure in column 15, lines 55-65)

Claims 9-48 are rejected on substantially the same basis as claims 1-6 above.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Astorino whose telephone number is 571-272-4723.

The examiner can normally be reached on Monday-Friday, 8:30AM to 3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michael Astorino  
July 9, 2006